

In the United States Court of Federal Claims

No. 01-064V

E-Filed Under Seal: April 29, 2015

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MAREK MILIK and JOLANTA MILIK, )  
legal guardians and parents of A.M., )  
Petitioners, ) Vaccine Injury; Motion for  
  ) Review; Causation-in-Fact; MMR  
  ) Vaccine; Onset of Symptoms  
v. )  
  )  
SECRETARY OF HEALTH AND )  
HUMAN SERVICES, )  
  )  
Respondent. )  
  )

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Robert J. Krakow, New York, N.Y., for petitioners.

Lisa A. Watts, Senior Trial Attorney, with whom were Joyce R. Branda, Acting Assistant Attorney General, Rupa Bhattacharyya, Director, Vincent J. Matanoski, Deputy Director, and Gabrielle M. Fielding, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for respondent.

OPINION AND ORDER

CAMPBELL-SMITH, Chief Judge

Petitioners, Marek and Jolanta Milik, seek review of a decision in which the special master denied compensation for their claim that their son, A.M., suffered severe neurological injuries as a result of a measles, mumps, and rubella (MMR) vaccination.

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<sup>1</sup> Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, this Opinion initially issued under seal to provide the parties the opportunity to object to the public disclosure of information contained within it. Neither party requested any redactions. The Opinion is thus reissued for publication in its entirety.

A.M. received the MMR vaccination at issue on January 29, 1998, at which time he was four years and one month old. A.M. is now just over twenty-one years of age.<sup>2</sup>

On review, the question for this court is whether the special master's decision that petitioners did not show by a preponderance of the evidence that that their son's injury was caused by the MMR vaccination was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. For the reasons set forth below, the court finds that petitioners have not shown that the special master's decision was arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law, and thus **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master.

## I. Background

### A. Procedural History

In January 2001, petitioners<sup>3</sup> filed a petition under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), codified as amended at 42 U.S.C. § 300aa-1 to -34 (2012), in which they alleged that A.M. suffered injuries including "spastic diplegia (paraplegia) causing [A.M.] to walk with a permanent and debilitating limp, severe gross and fine motor difficulties as well as difficulties learning," all of which were "caused-in-fact by administration of the MMR vaccination." Pet. 1, ECF No. 1.

In June 2001, respondent, the Secretary of Health and Human Services, filed a report opposing the petition for compensation. Resp't's Report, ECF No. 6.

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<sup>2</sup> As noted by the special master, although A.M. is now of age, he is a person with a disability requiring guardianship, and thus his parents continue to represent him in this matter. Decision 8 n.6, ECF No. 165.

<sup>3</sup> The petition was filed by Mr. Milik. Pet., ECF No. 1. In July 2013, Mrs. Milik joined the suit and the case caption was amended to reflect her participation. Decision 8 n.6. For ease of reference, the court refers to petitioners in the plural, regardless of whether a document was filed before or after Mrs. Milik joined the suit.

From January 2001 to March 2014, petitioners filed exhibits 1-38A,<sup>4</sup> including medical records (Exs. 1-8, 10-19, 21, 25, 27, 38, 38A<sup>5</sup>), school records (Exs. 9, 20), expert reports, with curriculum vitae (Exs. 22, 24, 30-31), medical literature (Ex. 24, (references 1-140), 28-29, 32-34), various documents unrelated to entitlement (Exs. 26, 35-37), and an index (Ex. 23).

From March 2008 to February 2013, respondent filed exhibits A-H, including expert reports, with curriculum vitae (Exs. A-D), medical literature (Exs. E-F, H), and MMR vaccine information (Ex. G). In addition, respondent filed a copy of the Denver Developmental Screening Test (Denver test) as Exhibit 1 to its report opposing compensation. Resp't's Report, Ex. 1.

The special master held a fact hearing on June 24, 2004, at which both A.M.'s parents testified. Tr., ECF No. 22 (1-Tr.).<sup>6</sup>

Petitioners' initial expert, Dr. Adrian Logush, wrote a report dated October 10, 2007, which Petitioners filed on November 21, 2007. Ex. 22. On December 18, 2007,<sup>7</sup>

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<sup>4</sup> It is noted that petitioners' Exhibits 1-11 were first filed on paper, and later refiled electronically as Exhibits 12-22. For example, Exhibits 1 and 12 are the same document, as are Exhibits 2 and 13, and so on. Following the convention in the special master's decision, this Opinion cites to the later filed electronic exhibits, Exhibits 12-22, rather than the earlier filed paper exhibits, Exhibits 1-11.

Petitioners noted they erred in labeling two different documents as Exhibit 11, the Logush expert report from October 2007 and Logush clinic visit notes from February 2011. 2-Tr. 14-15. The 2007 Logush expert report was later refiled electronically as Exhibit 22. To avoid confusion, this Opinion follows the convention adopted by petitioners during the expert hearing, 2-Tr. 15, and by the special master in his Decision, Decision 7, and cites to the Logush expert report as Exhibit 22. Ex. 22, ECF No. 83-9. The Logush clinic visit notes, filed only one time, are cited as Exhibit 11. Ex. 11, ECF No. 82-1.

<sup>5</sup> Exhibit 38A is a clearer copy of Exhibit 38, which is a facsimile copy.

<sup>6</sup> This Opinion follows the convention adopted in the Decision, and cites to the June 24, 2004 fact hearing transcript as 1-Tr., and the March 7, 2013 expert hearing transcript as 2-Tr.

<sup>7</sup> The special master explained that the date of the status conference was more likely December 18, 2007, rather than November 21, 2007, as stated in his order. See Decision 33 n.29. The date on which the special master held the status conference is immaterial to this Opinion.

Dr. Logush, counsel for both parties, and Mr. Milik participated in a digitally recorded telephonic status conference convened by the special master. Order, Dec. 21, 2007, ECF No. 50. Dr. Logush responded to questioning about his October 2007 expert report from both the special master and respondent's counsel. Logush conf. 1-4.<sup>8</sup>

On November 10, 2011, petitioners' filed an expert report from their testifying expert, Dr. Nizar Souayah.<sup>9</sup> Ex. 24. On March 27, 2008 and March 5, 2012, respondent filed expert reports from Dr. Michael H. Kohrman. Exs. A, C.

On March 7, 2013, the special master held an evidentiary hearing at which petitioners presented expert testimony from Dr. Souayah, and respondent presented Dr. Kohrman. Tr., ECF No. 129 (2-Tr.). The parties filed post-hearing briefing from August to November 2013. ECF Nos. 147-48, 153.

On October 29, 2014, the special master issued his sealed decision denying compensation. ECF No. 164. Neither party proposed redactions, and the special master publicly reissued his decision on November 20, 2014.<sup>10</sup> Decision, ECF No. 165. The special master found that petitioners had failed to show that the MMR vaccination caused A.M.'s injuries, primarily because he accepted Dr. Kohrman's opinion that the onset of A.M.'s global developmental delay preceded his MMR vaccination (onset finding). Decision 13-23, 29-32. In the alternative, the special master found, that A.M. did not suffer an encephalopathy or encephalitis, *id.* at 23-26, that even if he did suffer such an injury, the more likely cause was an infection, *id.* at 27, and that the timing of A.M.'s first reported symptom of limping did not fit the timeframe discussed in the medical literature in the record, *id.* at 24-25, 28-29, 36.

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<sup>8</sup> A member of the special master's staff transcribed the portion of the status conference during which Dr. Logush clarified his opinion offered in his October 2007 expert report, and the special master filed the transcription as an attachment to his December 21, 2007 order. Decision 7. Like the special master, the court will refer to that attached transcription as the Logush conference (Logush conf.).

<sup>9</sup> It is noted that because the records of Drs. Vinh Nguyen and Martin Bialer (contained in Exhibits 25 and 27 respectively) were filed after both Dr. Souayah and Dr. Kohrman prepared their expert reports, neither expert addressed these records in their report. Both experts provided some hearing testimony on these records. 2-Tr. 57-58, 139-41 (Souayah); 2-Tr. 164-65, 189-92 (Kohrman).

<sup>10</sup> Although unpublished, the special master's decision is available through commercial electronic databases. See, e.g., Milik v. Sec'y of Health & Human Servs., No. 01-064V, 2014 WL 6488735 (Fed. Cl. Spec. Mstr. Oct. 29, 2014). As both parties cited to the page numbers in the document filed on the court's CM/ECF system, ECF No. 165, the court follows suit.

Petitioners filed a motion for review on November 28, 2014,<sup>11</sup> Pet’rs’ Mot., ECF No. 166, to which Respondent filed a response on December 18, 2014, Resp’t’s Resp., ECF No. 168. Petitioners object to the special master’s finding that the onset of A.M.’s global developmental delay preceded his MMR vaccination, and to the special master’s finding that respondent’s expert, Dr. Kohrman, was more credible and persuasive than petitioners’ expert, Dr. Souayah.<sup>12</sup> Pet’rs Mot. 7-14. In addition, petitioners object to the special master’s alternative findings that: (1) A.M. did not suffer an encephalopathy or encephalitis, (2) but if he did, the more likely cause of that injury was infection, and (3) the first symptom relied upon by petitioners was not timely. Id. at 15-18.

Respondent responds that petitioners’ assertions of error are limited to the special master’s factual findings, which are well-supported and entitled to deference. See Resp’t’s Resp. 3. Respondent adds that the medical records support the special master’s onset finding, and in the alternative, the special master correctly determined that petitioners had failed to establish that A.M. suffered from an encephalopathy or an encephalitis caused by the MMR vaccination. Id. at 13-19.

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<sup>11</sup> Petitioners attempt to argue that the arbitrary and capricious standard of review is unconstitutional, and the court must conduct a de novo review of the special master’s decision. Pet’rs’ Mot. 6-7. Petitioners claim a constitutional right under Article III for such review, as well as a common-law right based on a plaintiff’s rights in state court for tort claims brought against vaccine manufacturers for injuries. Petitioners rely on Bruesewitz v. Wyeth LLC, in which the Court held “that the National Childhood Vaccine Injury Act preempts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects.” Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1081 (2011).

Respondent correctly responds that a Vaccine Act claim does not bar a petitioner from later filing a claim in an Article III federal court, and that petitioners’ reliance on Bruesewitz is misplaced. Resp’t’s Resp. 11 n.10 (citing 42 U.S.C. § 300aa-11(a)(2)(A)). Respondent further responds—also correctly—that the Vaccine Act standard of review is clearly limited to the deferential arbitrary and capricious standard. Id.

<sup>12</sup> Petitioners attempt to incorporate the “the facts, analysis and argument, in [their post-hearing] submissions and attachments” into their motion for review. Pet’rs’ Mot. 2 (citing Motion, ECF No. 147, Reply, ECF No. 153). According to Vaccine Rule 24(b)(3), petitioners’ motion for review must conform to RCFC 5.4, which precludes a party from incorporating an earlier-filed brief or memorandum by reference, and instructs the court to “disregard any such incorporation.” RCFC 5.4(b)(3). Accordingly, the court’s consideration of petitioners’ objections to the special master’s decision is limited to the objections and arguments presented in its motion for review.

## B. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if a petitioner proves, by a preponderance of evidence, all of the elements set forth in Section 300aa-11(c)(1), and that (per the language of the statute) there is not a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. A petitioner can recover in one of two ways: either by proving an injury listed on the Vaccine Injury Table (Table) or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1),

Under the Table method of recovery, there is a presumption that the vaccine caused the injuries if the petitioner establishes that the onset or “significant aggravation” of predicate injuries occurred within a time period set by the Table for a vaccine included in the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i), -14(a). “If petitioner can make such a showing, causation is presumed and petitioner is deemed to have made out a prima facie case of entitlement to compensation under the Act.” Whitecotton v. Sec'y of Health & Human Servs., 81 F.3d 1099, 1102 (Fed. Cir. 1996).

To establish a prima facie case when proceeding on a causation-in-fact theory, as petitioner attempted to do here, a “petitioner [must] prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). “[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’” Id. at 1352-53 (quoting Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (per curiam)). Stated another way, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” id. at 1353 (quoting Grant, 956 F.2d at 1148), and “[t]his logical sequence of cause and effect must be supported by a sound and reliable medical or scientific explanation,” Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (internal quotation marks omitted); see also 42 U.S.C. § 300aa-13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”). However, medical or scientific certainty is not required. Knudsen, 35 F.3d at 548-49.

In Althen v. Sec'y of Health & Human Servs., the Federal Circuit distilled this precedent into a three-part test, holding that to prove causation-in-fact, a petitioner must provide “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). [T]hese prongs “must cumulatively show that the vaccination was a ‘but-for’

cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006).

Once a petitioner has established a *prima facie* case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). However, if a petitioner fails to establish a *prima facie* case, the burden does not shift. Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a *prima facie* showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan, 539 F.3d at 1353 (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.”).

### C. Evidence Before the Special Master

The special master’s decision sets forth A.M.’s medical history, the qualifications of both parties’ experts, and their opinions, in significant detail. See Decision 4-8, 10-12. This court focuses on that information relevant to its review.

#### 1. Medical History

The court’s review of the medical history in this case is informed by review of the special master’s decision, the parties’ briefs, and the medical records filed by petitioners. See Decision 4-8; Pet’rs’ Mot. 2-6, Resp’t’s Resp. 3-8; Exs. 11-21, 25, 27 & 38A.

##### a. Early Care

A.M. was born on December 5, 1993. Ex. 12. From March 6, 1995 to December 11, 1995, A.M. visited the Addabbo Family Health Center (Addabbo Center) on several occasions for routine matters, including well-child examinations. Ex. 13, at 1-4. Subsequently, A.M. visited Dr. Mitchell Weiler on a number of occasions from April 25, 1996 to March 2, 1998 for well-child examinations, immunizations, and various health issues. Ex. 14, at 1-2, 8, 10, 13-14. A.M. received the MMR vaccination in Dr. Weiler’s office on January 29, 1998. Id. at 9-10.

On February 9, 1998, eleven days after his MMR vaccination, A.M. returned to Dr. Weiler with a complaint of a “sore throat.” Id. at 13. Dr. Weiler diagnosed A.M. with pharyngitis (throat swelling) and otitis media (ear infection), and treated him with an antibiotic. Id.; see also 2-Tr. 107 (Souayah); 2-Tr. 158 (Kohrman).

On February 23, 1998, A.M.’s ears were re-checked. Ex. 14, at 13. In addition, A.M. was “noted to have a limp [and was] seen by podiatry [and] x-rays were negative.” Id. The limp was reported as starting “last Friday,” id., which would have been Friday, February 20, 1998.

On March 2, 1998, A.M. returned to Dr. Weiler’s office with complaints of continued limping. Id. at 14. Dr. Weiler referred A.M. to an orthopedist, Dr. Bennett Futterman, who reported, on March 2, 1998, that although A.M. had “full symmetrical range of motion of the hips and knees,” he had an abnormal gait, and recommended that A.M. see a neurologist and perhaps a pediatric orthopedist. Ex. 17, at 44-45. Dr. Weiler referred A.M. to a pediatric neurologist, Dr. Joseph Maytal. See Ex. 15, at 3.

b. Dr. Joseph Maytal, Pediatric Neurologist

Dr. Maytal first examined A.M. on March 2, 1998. Id. at 1. Dr. Maytal’s report and summary of his initial examination noted a history of limping that began about one week earlier after A.M. “fell while running after another child,” a fall that A.M.’s parents described as “trivial.” Id. Dr. Maytal evaluated A.M. on various developmental achievements:

In the office he was able to awkwardly copy a circle. He could not copy a cross or a square. He could not pick the longest line of three out of three. He knew colors. He did not understand cold but he understood tired and hungry. He recognized colors. He could follow simple directions. He [k]new his first name and not his last name. Parents are not sure if he can use plurals. . . .

. . . He was able to identify and name pictures. He knew body parts.

Id. at 1-2. Dr. Maytal offered a provisional diagnosis of “Ataxia/Unsteadiness” and “Developmental Delay.” Id. at 3. He opined that A.M. had two issues:

One is the longstanding issue of this youngster who is globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills . . . The second issue is his acute symptoms of “limping”. As a precaution I would like to consider the reason for this limping as ataxia and evaluat[e] him with an MRI.

Id. at 2.

A.M. returned to Dr. Maytal on March 25, 1998, who opined that an MRI of A.M.’s brain taken the previous day showed “diffuse white matter demyelination which is consistent with demyelinating process most likely some form of leukodystrophy.” Id. at 5.

On March 3, 2014, sixteen years after his initial examination of A.M., Dr. Maytal authored a clarification of his initial diagnosis. See Ex. 38A. Dr. Maytal was then the Chief of the Division of Pediatric Neurology for the Cohen Children’s Medical Center of New York, at which A.M. remained a current patient for a “neurodegenerative disorder, unclear etiology.” Id. Dr. Maytal provided a clarification of the term that had become a key part of respondent’s argument—the “longstanding issue” of global developmental delay. Dr. Maytal wrote that “the used term ‘longstanding’ should be interpreted as ‘a condition existing prior to the examination.’ We are unable to determine the time length of symptoms.” Id.

#### c. IBR Interdisciplinary Treatment

In Summer of 1998, Dr. Maytal referred A.M. to the George A. Jervis Clinic, New York State Institute for Basic Research in Developmental Disabilities (IBR), Ex. 17, at 1, where A.M. had extensive interdisciplinary evaluations and testing. A.M. was seen by three different doctors, including a pediatric neurologist (Dr. Krystyna Wisniewski), a medical geneticist (Dr. Susan Sklower Brooks), and a neurologist (Dr. Ricardo Madrid). Id. at 1-3, 7-9, 16-18, 79-81.

On July 29, 1998, A.M. was evaluated by Dr. Wisniewski to “[d]etermine [the] etiology of his developmental disability.” Id. at 7. Dr. Wisniewski recorded a past medical history from A.M.’s parents that included the report that he “had some possible speech delay,” as well as that “[t]here is no history of regression in cognitive function. He is continuously improving with age.” Id.

According to Dr. Wisniewski’s examination of A.M.’s “[m]ental [s]tatus,” A.M.’s “cognitive function seems to be appropriate for his chronological age. He knows colors, numbers, and follows three step commands. His visual perception seems to be impaired; he just makes a circle and cross.” Id. at 8. In the past medical history, however, Dr. Wisniewski recorded that A.M. “had an ophthalmological examination which . . . appears to be normal.” Id. at 7. In the section titled “Developmental Milestones,” located on her report between “Birth History,” and “Past Medical History,” Dr. Wisniewski wrote “[m]ilestones were normal,” with no additional information. Id.

Dr. Wisniewski’s impression was one of “[s]pastic diplegia, more right than left; mild cerebellar signs, etiology to be determined.” Id. at 9.

Also on July 29, 1998, A.M. was evaluated by Dr. Brooks for suspected leukodystrophy. Id. at 16. Dr. Brooks recorded a history that included that A.M.'s parents felt he was developing normally until February 1998, when he first developed a limp, and that they "do not feel that [A.M.] has had any regression in his cognition." Id. Dr. Brooks opined that his "clinical history is suggestive of MLD [metachromatic leukodystrophy]," and that "[a] rare complication of measles vaccination could be SSPE [subacute sclerosing panencephalitis]. However, the usual presentation is one of dementia and seizures followed by motor loss." Id. at 18.

On September 23, 1998, A.M. was evaluated by Dr. Madrid for the purpose of "a neuromuscular evaluation and nerve conduction studies to [rule out] putative peripheral neuropathy." Id. at 1-3, 75. A.M.'s parents reported to Dr. Madrid that "[s]ince the onset of his difficulties, . . . [A.M.] has not shown any cognitive regression and that his gait difficulties, if anything, have improved since March of this year rather than deteriorat[ing]." Id. at 1. According to Dr. Madrid's assessment,

[t]he chronology of symptoms provided and the clinical signs are suggestive but not diagnostic of post infectious or post vaccination acute disseminated encephalomyelitis. . . . The neurological complication associated with MMR vaccination could be encephalitis or an encephalopathy, though the latter is usually associated with an altered mental state and seizures in a background of fever, symptoms which are not noted at the time.

Id. at 3.

On October 1, 1998, A.M. had a MRI examination of his brain, which Dr. Wisniewski compared with the initial MRI taken a little more than six months earlier, on March 24. Id. at 90. Her impression was that there was "[n]o interval change compared to 3/24/98. . . . The imaging findings are again in keeping with dysmyelinating disease." Id.

Finally, on November 17, 1998, the IBR interdisciplinary treatment team met to discuss A.M.'s diagnosis and treatment plan. Id. at 79-81. In a letter to Dr. Maytal, the treatment team characterized A.M.'s diagnosis as "[d]iplegia . . . [t]he etiological diagnosis is most likely S[tatus]/P[ost] Infectious Encephalitis." Id. at 80.

d. Bilingual Psychological Evaluation<sup>13</sup>

On September 7, 1998, A.M. received a bilingual psychological evaluation from Maria Malinowska, Ph.D. Ex. 19, at 5-9. Dr. Malinowska reported that “[A.M.’s] gross motor coordination was impaired: he walked with difficulty and with an unsteady gait. His fine motor coordination was likewise impaired; he was neither able to put a bean on a stick, to draw a circle nor any recognizable form with a pencil.” Id. at 6. Nor could A.M. point accurately to all body parts. Id. at 8.

Dr. Malinowska evaluated A.M.’s development using the Vineland Adaptive Behavior Scales. Id. at 7. On the date of the examination, A.M. was four years and nine months of age. Id. at 1. Dr. Malinowska wrote that her “[o]verall analysis of Vineland Adaptive Behavior Scales indicates a definite weakness in the area of communication and motor skills and a mild weakness in the area of daily living skills.” Id. at 8. Dr. Malinowska evaluated his achievements on the socialization domain to be “age appropriate.” Id. She considered his achievements on both the communication and daily living skills domains to be moderately low (communication: age two years, six months; daily living skills: three years, two months), and his achievements on the motor skills domain to be low (two years, ten months). Id. at 7-8. In her summary, Dr. Malinowska reported that A.M. “experiences motor and speech/language difficulties as well as attentional problems. These difficulties which are most likely due to an organic brain dysfunction interfere with his intellectual and adaptive functioning.” Id. at 9.

e. Recent Medical Records

As noted by the special master, the medical records filed in this case provide little information about A.M.’s care in the years immediately following 1998. Decision 7. In November 2012, petitioners filed additional medical records for an MRI in 2005, and for medical examinations in 2011 and 2012. Exs. 25 & 27.

In 2011 and 2012, A.M. returned to the Cohen Children’s Medical Center for follow-up evaluations for his neurodegenerative disorder, where he was seen by a pediatric neurology fellow, Dr. Simona Proteasa. Ex. 27, at 1-11. The attending physician with whom Dr. Proteasa conferred on two of A.M.’s three visits was Dr. Maytal, A.M.’s first pediatric neurologist. Id. at 4 (Oct. 20, 2011 visit); id. at 6 (Mar. 15, 2012 visit).

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<sup>13</sup> A.M. was raised in a Polish speaking home and spoke only Polish with his parents. Ex. 17, at 16-17 (stating that as of July 1998, “[A.M.] has picked up some English receptively, but does not speak any English”). “A.M. stayed at home with his mother and had very limited contacts with children until the age of four when he was enrolled in prekindergarten.” Ex. 19, at 5. A.M. attended prekindergarten twelve hours per week from September 1997 to January 1998. See Ex. 20, at 166.

Dr. Proteasa reported that A.M. first had an MRI of the brain in 1998, which showed “white matter suggestive of demyelinating etiology,” with at least three repeated brain MRIs, which “showed no progression of the disease.” Id. at 1. Dr. Proteasa’s impression was that A.M. had a “history consistent with disseminated encephalitis versus encephalomyelitis likely autoimmune in etiology.” Id. at 3.

On October 1, 2011, a radiologist, Dr. Vinh Nguyen, performed a noncontrast enhanced brain MRI on A.M. Ex. 25, at 15. He noted that A.M. had a history of “Dystonia [and] Encephalopathy.” Id. Dr. Nguyen opined that his findings were “suggestive of a metabolic abnormality versus toxic encephalopathy. Of metabolic abnormalities, findings may represent a stage disease for metabolic abnormalities affecting the white matter, and may include vanishing white matter disease.” Id. His impression was “[d]iffuse abnormal parenchymal signal abnormality reminiscent of a toxic versus metabolic encephalopathy.” Id.

Finally, on March 29, 2012, A.M. was examined by a specialist in medical genetics, Dr. Martin Bialer, who reported A.M.’s complaints as “spastic ataxic dystonic quadriplegia, insomnia and symptoms of encephalopathy.” Id. at 3. He reported that an “MRI scan of the brain done [on] 3/24/98 revealed severe demyelination/dysmyelination which did not change on followup exams.” Id. Dr. Bialer’s impression was that

[t]he finding of apparently normal development followed by a sudden loss of abilities following an insult with severe demyelination is suggestive of vanishing white matter disease. This often presents during childhood with ataxia following infection or fright. There is episodic deterioration. It is caused by mutations in one of 5 EIF2B genes, which are transcription initiation factors. These genes are responsible for 90% of cases. The condition is inherited as an autosomal recessive. The possibility of this diagnosis was suggested by Dr. Nguyen on his last MRI scan and, in my opinion, is a good fit for clinical presentation.

Id. at 4 (referring to Ex. 25, at 15).

At the time of this visit, A.M. was reported to be in a wheelchair, unable to walk or stand, or to feed himself. Id. at 3.

## 2. Experts

### a. Dr. Adrian Logush, Petitioners’ Initial Expert<sup>14</sup>

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<sup>14</sup> As petitioners did not file a curriculum vitae for Dr. Logush, there is little available information on his background.

Dr. Logush is a pediatric neurologist with the IBR, Ex. 22, at 1, at which A.M. first received extensive testing and evaluation in 1998. In October 2007, Dr. Logush provided petitioners with an expert report in which he opined that:

The acute onset of neurological signs and symptoms, and extensive negative diagnostic work-up to date for leukodystrophy are suggestive but not diagnostic of post infectious or post vaccine, immunologically induced acute disseminated encephalitis vs. encephalomyelitis.

Id.

During the December 2007 status conference, Dr. Logush said that while he had examined A.M. prior to offering his expert report, he had not been treating him, and that he came “on board only in July [2007] and I had to review the case and to see if every possible test that was ordered in the past was done and the results of it and to see if there was anything else that could possibly be set up.” Logush conf. 3.

Dr. Logush explained that the term “post infectious” in his October 2007 expert report should be understood to mean an infection resulting “from the vaccine.” Id. at 1. He reiterated that the many medical tests performed to identify A.M.’s condition had yielded negative results. This outcome was “highly suggestive . . . of the post-vaccine immunologically induced encephalitis.” Id. at 1-2. Finally, Dr. Logush stated that vaccine causation of A.M.’s encephalitis was “very probable,” which meant “more than 50 percent likelihood.” Id. at 2.

In February 2011, Dr. Logush saw A.M. for a neurology follow-up examination, and petitioners filed his notes from that clinic visit. Ex. 11, at 1. In those clinic notes, Dr. Logush repeated, word for word, the assessment he provided in his initial October 2007 expert report, specifically that “[t]he acute onset of neurological signs and symptoms and extensive negative diagnostic work-up to date for leukodystrophy are suggestive but not diagnostic of post infectious or post vaccine, immunologically induced acute disseminated encephalitis vs. encephalomyelitis.” Id. Dr. Logush notably did not repeat the opinion he provided during the December 2007 status conference, namely that the vaccine causation of A.M.’s encephalitis was “very probable.”

Dr. Logush did not testify at the March 2013 evidentiary hearing.

b. Dr. Nizar Souayah, Petitioners’ Testifying Expert

Since 2004, Dr. Souayah has served as the Director of both the Peripheral Neuropathy Center and EMG laboratory of the Neurology Department, University Hospital, New Jersey Medical School. Ex. 31, at 4. Since 2006, he has also served as

Program Director for the Neuromuscular Medicine Fellowship program at the New Jersey Medical School. Id. Dr. Souayah is board-certified in neurology, electrodiagnostic medicine, and neuromuscular medicine. Id. at 1-2. Within his field of expertise, he has published more than 180 professional abstracts and reports, as well as 2 books. Id. at 13-21; 2-Tr. 8. Furthermore, since 2010 Dr. Souayah has served as the Executive Editor of the Journal of Vaccines & Vaccinations, and also serves as an ad hoc reviewer for 28 named publications, including the journal Vaccine. Ex. 31, at 3-4.

In both his expert report and his testimony, Dr. Souayah contended that it was his opinion that the MMR vaccine caused A.M.'s injury chiefly because: (1) A.M. enjoyed normal health and development before the vaccine; (2) A.M. displayed the first symptom of his injury, limping, about 22 days after receiving his MMR vaccination; (3) no other cause for A.M.'s injury was identified, despite extensive testing; and (4) the MMR vaccine has been suspected of causing central nervous system damage. Ex. 24 ¶¶ 43, 53, 62-63, 65-66, 72-73; 2-Tr. 18-20, 60-61, 87.

Dr. Souayah acknowledged that he could not specify the exact mechanism by which the vaccination injured A.M., but suggested several possibilities. Ex. 24 ¶¶ 57, 60-61; 2-Tr. 85-87.

During the hearing, Dr. Souayah testified that A.M suffered from spastic diplegia, developmental delay, and encephalitis or an encephalopathy resulting in white matter changes in his brain, all of which began after his MMR vaccination. 2-Tr. 130. In his expert report, Dr. Souayah stated that A.M. developed acute static spastic diplegia, global mental delay, extensive white matter disease, and global mental retardation, all of which started within 22 days after receipt of the MMR vaccination. Ex. 24, ¶¶ 35, 43, 53, 62 & 73.

c. Dr. Michael H. Kohrman, Respondent's Expert

Dr. Kohrman is board-certified in neurology and psychiatry, with a special competency in child neurology and sleep medicine, and also board-certified in pediatrics. Ex. D, at 3; 2-Tr. 143-44. Since 2000, Dr. Kohrman has served as the Director of Pediatric Clinical Neurophysiology at the University of Chicago Children's Hospital, and is also a Professor of Pediatrics, Neurology and Neurosurgery at the University of Chicago. Ex. D, at 1. Furthermore, Dr. Kohrman serves as the Medical Director of the Epilepsy Unit of Hinsdale Hospital, and as the Director of both the Tuberous Sclerosis Clinic and the Pediatric Epilepsy Program, at the University of Chicago. Id. He has published more than 100 book chapters, professional abstracts, presentations, and peer reviewed publications. Id. at 17-29.

In March 2008, Dr. Kohrman provided a responsive expert report to both Dr. Logush's October 2007 expert report and the clarifications Dr. Logush offered during

the December 2007 status conference. Ex. A. In February 2012, Dr. Kohrman provided a responsive expert report to Dr. Souayah's November 2011 expert report. Ex. C.

In both reports, Dr. Kohrman opined that A.M. had a "preexisting global developmental delay documented by Drs. Maytal, Brooks, and Malinowska[,] . . . [which] predated the MMR vaccination." Ex. A, at 5; Ex. C, at 8.

Dr. Kohrman opined at the hearing that A.M.'s delay began before he received the MMR vaccine, and that there is "no evidence that the MMR [vaccination] caused his neurologic problems." 2-Tr. 148. Having reviewed A.M.'s medical records from 2011 and 2012, Exs. 25 & 27, Dr. Kohrman opined that a diagnosis of vanishing white matter disease could explain A.M.'s injury in 1998, as well as his current condition. 2-Tr. 164-65.

Alternatively, Dr. Kohrman opined that the "history of sore throat makes a post infectious acute disseminated encephalomyelitis an alternate cause for A.M.'s acute changes and limp [and] a diagnosis of acute disseminated encephalomyelitis [is] entertained in this case." Ex. A, at 5; 2-Tr. 168-69.

## II. Jurisdiction and Standard of Review

In response to a motion for review of a decision issued by a special master, this court has jurisdiction "to undertake a review of the record of the proceedings," and may subsequently take one of three actions:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious,<sup>15</sup> an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2) (footnote added); see also Vaccine Rule 27. As "[t]he issue before the special master . . . was whether the evidence submitted by the petitioner warranted a conclusion that the vaccine caused the injury[,] [t]he review applicable to

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<sup>15</sup> Petitioners assert that a "decision is arbitrary and capricious when it is 'unsupported by substantial evidence.'" Pet'rs' Mot. 7 (citing 5 U.S.C. § 706 (5)). Section 706 governs judicial review of agency action, and is thus inapplicable to this court's review of the special master's decision.

this determination is under the ‘arbitrary and capricious’ standard.” Hines v. Sec’y of Health & Human Servs., 940 F.2d 1518, 1527 (Fed. Cir. 1991).

The arbitrary and capricious standard of review is difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact. In general, reversible error is “extremely difficult to demonstrate” if the special master “has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.”

Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000) (quoting Hines, 940 F.2d at 1528). When a party’s

testimony supports the special master’s finding on [a] point, . . . although [the opposing party may] contend that the more compelling evidence is to the contrary, we do not sit to reweigh the evidence. [Where] the special master’s conclusion was based on evidence in the record that was not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.

Id. at 1363. “[W]e do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.” Munn v. Sec’y of Health & Human Servs., 970 F.2d 863, 871 (Fed. Cir. 1992).

As the Federal Circuit has stated,

Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. . . . That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Hodges v. Sec’y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted).

Nonetheless, “[w]e do not say that this is a burden no petitioner can carry. It is possible to hypothesize a case, for example, in which a special master rendered a decision when no factual basis whatever existed under which the decision could be justified.” Munn, 970 F.2d at 871. However, “arguments as to the weighing of evidence, particularly where, as here, witness credibility is involved, do not demonstrate reversible error.” Hines, 940 F.2d at 1527.

### III. Discussion

Petitioners make a total of five objections, of which four are to the special master's primary finding that the onset of A.M.'s global developmental delay preceded his MMR vaccination. See Pet'rs' Mot. 1-2, 7-18. Petitioners object that the special master acted arbitrarily and capriciously when he:

- improperly interpreted noncontemporaneous medical records (the history section of Dr. Malinowska's bilingual evaluation), and misconstrued contemporaneous pediatric records (the Addabbo Center's and Dr. Weiler's examinations) to find that A.M.'s developmental delay predated his MMR vaccination;
- disregarded Dr. Maytal's clarification of the term "longstanding" in his original diagnosis of A.M., and instead relied on his own "improperly expansive" interpretation of the term;
- relied exclusively on A.M.'s alleged speech delay to determine the onset of his injury, which petitioners claim was "primarily a complex motor problem, spastic diplegia;" and
- mischaracterized Dr. Souayah's opinion, selectively emphasizing immaterial errors while arbitrarily failing to properly account for the contemporaneous medical record on which the expert appropriately relied.

Id. at 1-2.

Petitioners also make one objection to the special master's alternative findings, that A.M did not suffer an encephalopathy or encephalitis, that if he did suffer such an injury, the more likely cause was an infection, and that the onset of A.M.'s limping occurred outside the accepted timeframe for such an injury. See id. at 2, 15-18.

Petitioners' objections all concern either the special master's weighing of evidence, or his credibility determination of each party's expert. Accordingly, this court reviews petitioners' objections under the deferential arbitrary and capricious standard. See Lampe, 219 F.3d at 1360; Hines, 940 F.2d at 1527.

- A. The Special Master's Finding that the Onset of A.M.'s Global Developmental Delay Preceded A.M.'s MMR Vaccination
  1. Petitioners' Objection to the Special Master's Interpretation of Certain Medical Records

Petitioners object to the special master's use of certain medical records to support his onset finding that A.M.'s global developmental delay preceded his MMR vaccination. In particular, petitioners contend that the special master "misconstrued" the meaning of the developmental notes in A.M.'s contemporaneous, pre-vaccination pediatric examinations, conducted at the Addabbo Center and by Dr. Weiler, when the special master accepted Dr. Kohrman's opinion that those records showed developmental delay. See Pet'rs' Mot. 7-8, 10, 15. Petitioners insist that "[t]he contemporaneous records reveal no finding by A.M.'s pediatricians . . . that A.M. had abnormal development prior to January 29, 1998." Id. at 3 (citing Exs. 13, 14).

In his opinion, Dr. Kohrman reviewed the notations by both the Addabbo Center pediatricians and Dr. Weiler, and interpreted both to show delay. See 2-Tr. 151-52. The special master accepted Dr. Kohrman's opinion. See Decision 18-19.

With respect to the Addabbo Center records, Dr. Kohrman opined that they showed possible regression in A.M.'s language development between the ages of fifteen months and two years:

According to [respondent's expert], the signs of A.M.'s developmental delay stretch as far back as his early pediatric records from the Addabbo Family Health Center. (2-Tr. 151-52.) Comparing the records of A.M.'s 15-month and 2-year visit (Ex. 13, pp. 1-4), Dr. Kohrman points out that at 15 months A.M.'s pediatrician "check marked" that A.M. had achieved a milestone of "3-6 words" (2-Tr. 151-52; Ex. 13, p. 1), while at his 2-year visit the "3-6 words" milestone is not check-marked (Ex. 13, p. 4). Instead, Dr. Kohrman points out that the 2-year visit indicates, under the "4-10 words" milestone, that A.M. says "mama" and "dada." (2-Tr. 151-52.) Dr. Kohrman argues that these records show not only a lack of progress, but a possible regression, to the extent that A.M. may have gone from 3-6 words to just two, "mama" and "dada." (Id.)

Decision 18.

But a review of these records fails to support Dr. Kohrman's interpretation. The fact that the pediatrician wrote two words next to "4-10 words" would seem to indicate a notation about that achievement, and not the "3-6 words" achievement. See Ex. 13, at 4. If A.M. did speak only two words (mama, dada), there would be no reason for the pediatrician to write those words next to the "4-10 words," achievement. Indeed, the special master also appears to have adopted this interpretation in the Fact section of the Decision: "With regard to development, [the Addabbo Center pediatrician] noted that A.M. responded to sound, used 4 to 10 words ("mama" and "dada" were noted specifically), walked up stairs, and walked independently." Decision 4 (citing Ex. 13, at 4).

Thus to the extent that the special master accepted the inference offered by Dr. Kohrman that the Addabbo Center records show delay, the requisite record support is wanting, as more fully discussed infra Part III.A.6, but not sufficient to compel a different decisional outcome.

With respect to the records of Dr. Weiler, Dr. Kohrman pointed to the notations in a spring 1996 examination conducted by Dr. Weiler:

[O]n April 25, 1996, A.M. was seen by a new pediatrician, Dr. Weiler, at two years, four months, of age. (Ex. 14, p. 1.) His developmental progress was listed as “several words.” (Id.) According to Dr. Kohrman, by this age A.M. should have been speaking in short phrases and simple sentences. (2-Tr. 151.) Moreover, Dr. Kohrman . . . argues that if A.M. was developing normally, he should have achieved two-word phrases and know[ledge] [of] body parts by two years and four months of age. There is no indication in Dr. Weiler’s evaluation of “several words,” however, that A.M. had achieved these milestones. Nor were they previously checked off on the Addabbo forms during earlier pediatric visits. (Id.; Ex. 13, pp. 1, 4; Ex. 14, p. 1.)

Decision 18-19.

Review of Dr. Weiler’s examination notes show that his developmental assessment of A.M. was recorded succinctly as: “Dev: several words.” Ex. 14, at 1. There is no indication in Dr. Weiler’s notes that he made other efforts to evaluate A.M.’s development. In the Denver test, the developmental screening test relied upon by Dr. Kohrman, there are four categories of development—personal/social, fine motor-adaptive, language, and gross motor. See Denver test. Absent from Dr. Weiler’s notes is any mention of A.M.’s development in the three non-language domains, and the observation about A.M.’s language development was limited to the brief notation “several words.” Nor is there an indication in Dr. Weiler’s notes regarding how he evaluated A.M.’s speech at the time of the April 1996 examination, when A.M. did not speak English. See supra note 14.

Dr. Kohrman’s opinion regarding A.M.’s speech delay is based in part on Dr. Kohrman’s assumptions that: (1) Dr. Weiler attempted to assess A.M.’s development; and (2) A.M.’s lack of English posed no barrier to his doing so. The content of Dr. Weiler’s examination record, however, fails to support either assumption.

The court finds that Dr. Kohrman’s inference, that Dr. Weiler’s spring 1996 examination record shows delay, which the special master accepted, is poorly supported,

but—as discussed *infra* Part III.A.6—is not enough to disturb the special master’s decision.

Petitioners also object to the special master’s interpretation of the developmental history provided by A.M.’s parents to Dr. Malinowska. See Pet’rs’ Mot. 13-14. Petitioners assert that the special master’s interpretation was improper. *Id.*

Dr. Malinowska recorded a history that indicated A.M. began speaking in “simple sentences at the age of three.” Decision 19 (citing Ex. 19, at 5). The special master said that according to Dr. Kohrman, A.M. should have achieved this milestone by age two and one-half, thus “this in itself identifies a six-month delay, which indicated developmental delay long before A.M. received his January 1998 MMR vaccination at age four.” *Id.* (citing 2-Tr. 155-56.).

According to petitioners, “[b]ased upon this one isolated historical description of a mild speech delay that occurred almost two years earlier, the Special Master concluded that A.M. had developmental delay long before the MMR vaccination,” Pet’rs’ Mot. 13, and that “[e]ven if this non-contemporaneous reporting is accurate . . . the mild six-month delay hardly explains the ataxia and profound motor problems that A.M. developed after the MMR vaccination,” *id.* at 14 (footnote omitted).

But petitioners’ description of Dr. Malinowska’s evaluation wholly ignores her findings of delay in three different domains, as well as the lack of mention by A.M.’s parents’ reports of any regression. Petitioners also overlook the special master’s reliance on Dr. Maytal’s evaluation, and the two MRI studies of A.M.’s brain. See infra Parts III.A.2, III.A.5. Petitioners are simply incorrect that the special master based his conclusion that A.M.’s global developmental delay preceded the MMR vaccination only on the history recorded in Dr. Malinowska’s examination record.

## 2. Petitioners’ Objection to the Special Master’s Rejection of Dr. Maytal’s Later-Offered Clarification, and the Special Master’s Interpretation of the Term “Longstanding”

Petitioners strenuously object both to the special master’s rejection of Dr. Maytal’s clarification of the term “longstanding” in his initial diagnosis, as well as to the special master’s interpretation of that term to mean that A.M.’s global developmental delay preceded his January 29, 1998 MMR vaccination. Pet’rs’ Mot. 7-13.

With regard to the special master’s rejection of Dr. Maytal’s clarification, petitioners have two objections. First, petitioners take exception to the special master’s characterization of Dr. Maytal’s clarification as “litigation driven.” *Id.* at 9; see also Decision 17 (“There are several reasons why I should not credit Dr. Maytal’s later, litigation-driven letter . . . ”). Second, petitioners object that the special master rejected

Dr. Maytal's clarification because it was a non-contemporaneous record. See Pet'rs' Mot. 9-10 ("Dr. Maytal's March 3, 2014, clarifying letter . . . should not have been rejected as a non-contemporaneous record because it was offered by Dr. Maytal to explain and clarify what he meant . . .").

Petitioners are mistaken as to both objections. While the special master did characterize Dr. Maytal's clarification as litigation-driven,<sup>16</sup> Decision 17, and did note that Dr. Maytal's clarification was "not contemporaneous to the events to which it speaks," Decision 17 n.14, the special master did not reject Dr. Maytal's clarification for either reason. Rather, the special master found that the meaning of longstanding urged by petitioners simply did not make sense within the context of Dr. Maytal's original diagnosis. See id. at 17.

Dr. Maytal first examined A.M. on March 2, 1998, thirty-two days after A.M.'s January 29, 1998 MMR vaccination. In petitioners' interpretation of Dr. Maytal's clarification, his report would be read to mean that the onset of A.M.'s global developmental delay could have been after his MMR vaccination, but before Dr. Maytal's examination, thus existing for fewer than thirty-two days.

First, the special master considered whether a period of time of about one month could be characterized as longstanding. The special master looked to the ordinary denotative meaning of the term "longstanding," which is "of long duration." Id. at 17 n.15. He interpreted this to "indicate that the delay had lasted substantially longer than one month." Id. at 17. The special master thus found unpersuasive an interpretation of the term longstanding that would include a period of time of less than one month.

Second, the special master pointed to the contrast in Dr. Maytal's two initial diagnoses, for global developmental delay and for onset of limping. Decision 17; see also Ex. 15, at 3 ("Provisional diagnosis: Ataxia/Unsteadiness[;] Developmental Delay").

The definition of "longstanding" suggested in Dr. Maytal's subsequent letter--i.e., as nothing more than "a condition existing prior to the examination"--would completely erase the distinction he originally drew between the "longstanding" global delay and the "acute" symptom of limping, and would make the original record incoherent as actually written.

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<sup>16</sup> It is noted that Dr. Maytal issued his clarification in a March 3, 2014 letter addressed "To Whom It May Concern," one year after the conclusion of the March 7, 2013 expert hearing, and just weeks before petitioners completed post-hearing briefing on March 27, 2014. See Ex. 38A. As the special master said in his Decision, "[f]or many years, it has been obvious that Dr. Maytal's notation of 'longstanding' developmental delay, based on his application of the Denver test, would play a key role in the resolution of this case." Decision 15 n.12. The special master's characterization of Dr. Maytal's clarification letter as "litigation-driven" was reasonable.

Decision 17. A.M. first began to limp on February 20, 1998, ten days prior to Dr. Maytal's examination. The special master simply found unpersuasive that Dr. Maytal would characterize the onset of an event ten days earlier (the limping) as acute, and characterize the onset of an event less than thirty-two days earlier (the time of onset urged by petitioners for A.M.'s global developmental delay) as longstanding. The special master rejected the possibility that a difference of fewer than twenty-two days in onset could result in the substantially different characterizations of acute and longstanding.

Petitioners also object to the special master's interpretation of the term longstanding as "improperly expansive." Pet'rs Mot. 11. But, as just discussed, the special master relied on the ordinary meaning of the term. See Decision 17 & n.15. In effect, the special master's interpretation was that longstanding meant more than thirty-two days, an interpretation that the court finds reasonable rather than improperly expansive.

### 3. Petitioners' Objection to the Special Master's Alleged Reliance on Record Evidence of Speech Delay to Determine the Onset of A.M.'s Global Developmental Delay

Petitioners object that the special master "relied exclusively on A.M.'s alleged speech delay" to determine the onset of his injury, which petitioners claim was "primarily a complex motor problem, spastic diplegia." Pet'rs' Mot. 2; id. at 15-17.

Petitioners' objection misstates the special master's decision. First of all, the special master relied on Dr. Maytal's diagnosis, see Decision 13-16, and Dr. Maytal did not limit his March 2, 1998 examination of A.M. to evaluating his language development. According to Dr. Maytal, "[i]n the office [A.M.] was able to awkwardly copy a circle. He could not copy a cross or a square. He could not pick the longest line of three out of three." Ex. 15, at 1. These achievements are listed on the Denver test as fine motor achievements. See Denver test. It was on the basis of this testing that Dr. Maytal diagnosed A.M. as being "globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills." Ex. 15, at 2 (emphasis added).

In addition, the special master relied on Dr. Malinowska's September 7, 1998 bilingual evaluation, in which she assessed A.M.'s achievements on three different domains to be less than his chronological age—communication, daily living skills, and motor skills. See infra Part III.A.5.

Petitioners' objection that the special master relied exclusively on A.M.'s alleged speech delay to determine the onset of his injury is simply incorrect.

4. Petitioners' Objection to the Special Master's Finding that Dr. Kohrman's Opinion Was More Persuasive than Dr. Souayah's Opinion

Petitioners object that the special master "misconstrued [Dr. Souayah's] analysis . . . in assessing his credibility." Pet'rs Mot. 2. According to petitioners, "[t]he Special Master primarily discredits Dr. Souayah because of his 'incorrect assumption' that A.M. was normal before the MMR vaccination." Id. at 17 (citing Decision 12).

Petitioners' essentially repeat their earlier objection to the special master's decision not to credit Dr. Souayah's interpretation of the term "longstanding" as used by Dr. Maytal. As discussed supra Part III.A.2, the special master's interpretation of that term was sound.

Petitioners are correct that the special master found that as "Dr. Souayah based his testimony on a clearly flawed assumption as to the time of the onset of A.M.'s neurological dysfunction, his causation opinion can be readily dismissed for that reason alone." Decision 22. Nonetheless, the special master engaged in further evaluation of both experts.

The special master also found that "Dr. Kohrman ha[s] far superior qualifications concerning the particular issues in this case," as Dr. Kohrman was a pediatric neurologist, board certified in pediatrics, while Dr. Souayah was a neurologist who "generally treats adults, not children." Id.

A primary issue in this case is whether A.M. was developmentally delayed prior to the vaccination in question. On this issue, Dr. Kohrman's qualifications are far better. As a pediatric neurologist, Dr. Kohrman sees children with neurological problems on a regular basis. Pediatric neurologists are the medical specialists most qualified to diagnose developmental delays in a child, more so even than pediatricians. . . . Dr. Souayah, on the other hand, has not diagnosed developmental delay in a child since his residency in 2002.

Id. at 22-23 (internal citations omitted).

Finally, petitioners also object that the special master "credits Dr. Kohrman over Dr. Souayah in the application of the Denver developmental screening tests." Pet'rs' Mot. 18 (citing Decision 15). The special master said that he found "the testimony of Dr. Kohrman more persuasive both because his testimony evinces a more detailed understanding of the application of the Denver test, and because he has superior credentials and experience in this area." Decision 16.

Petitioners argue that any difference between Drs. Souayah and Kohrman in their ability to administer and interpret the Denver test should be irrelevant in assessing their relative credibility, as Dr. Maytal never expressly stated he evaluated A.M. according to the Denver test, which would make interpretation of the Denver test unnecessary in this matter. See Pet'rs' Mot. 18 (citing Decision 16).

Petitioners' argument is directly contradicted by Dr. Souayah's hearing testimony, in which he agrees that Dr. Maytal administered the Denver test to A.M. See 2-Tr. 112-13.

Q -- it appears that Dr. Maytal used the Denver Developmental Screening Test in making these observations about [A.M.], doesn't it?

A It seems, yes.

Id. at 112 (discussing Ex. 15, at 1-2). Accordingly, petitioners' argument is unavailing.

5. The Special Master's Reliance on Record Evidence to Which Petitioners Did Not Object

It is noteworthy that a review of petitioners' objections shows that they did not object to certain other medical records upon which the special master based his onset finding. In particular, petitioners made no objection to the special master's use of the results of the bilingual psychological evaluation conducted by Dr. Malinowska, or to his reliance on Dr. Kohrman's interpretation of the repeated MRI studies of A.M.'s brain. See Decision 19-21.

Dr. Malinowska conducted a "bilingual psychological evaluation," during which she "assessed [A.M.'s] developmental status, taking into account the difficulties posed by his limited comprehension of English." Id. at 6 (citing Ex. 19, at 9). At the time of her September 7, 1998 examination, A.M. was four years nine months of age. Ex. 19, at 5.

Dr. Malinowska found A.M.'s developmental achievements to fall short for his chronological age on three out of the four domains of evaluation. Id. at 7-8. In the communication domain, Dr. Malinowska evaluated A.M. at two years, six months of age. Id. at 7. In the daily living skills domain, she evaluated A.M. at three years, two months, and in the motor skills domain, she evaluated him at two years, ten months. Id. at 7-8. Dr. Malinowska found A.M.'s development in the fourth domain of socialization to be age appropriate. Id. at 8.

As petitioners correctly pointed out, Dr. Malinowska said nothing about "longstanding developmental delay or motor dysfunction that predated the January 29,

1998, MMR vaccination" in her report. Pet'rs' Mot. 14. Taken alone, Dr. Malinowska's findings document A.M.'s delay only at the time of her September 1998 examination.

But Dr. Kohrman did not rely only on Dr. Malinowska's findings in his opinion. Rather, he also relied on the repeated assertions of A.M.'s parents, from July to September 1998, that A.M. suffered no regression in cognitive function since the onset of his limping. See Decision 19-20 (citing 2-Tr. 155-58). The special master carefully noted each such report.

In her report following A.M.'s exam of July 29, 1998, Dr. Wisniewski noted under past medical history that "there is no history of regression in cognitive function." (Ex. 17, p. 7.) In a report of an exam of the same date, Dr. Sklower Brooks also states that "the parents do not feel that [A.M.] has had any regression in his cognition." (Ex. 17, p. 16.) In addition, Dr. Madrid noted in his report of his September 23, 1998, exam of A.M. that "since the onset of his difficulties, the parents indicate that the child has not shown any cognitive regression." (Ex. 17, p. 1.) .

Id. at 20 n.18. Of note, Dr. Madrid's September 23 examination—the third time A.M.'s parents denied any regression—was after Dr. Malinowska's September 7 evaluation of A.M., so the record clearly shows that at the time of Dr. Malinowska's evaluation, A.M.'s parents felt his cognitive development had not regressed.

Given this lack of regression, and Dr. Malinowska's evaluation of developmental delay in three domains—communication, daily living skills and motor skills—Dr. Kohrman concluded that A.M. was developmentally delayed prior to the MMR vaccination:

Dr. Kohrman argues, had A.M. been developmentally normal up until his MMR vaccination at over four years of age, Dr. Malinowska's findings, placing A.M.'s skills at chronological age equivalents in the two-year range, would not be possible absent the type of regression that A.M.'s parents specifically reported as absent.

Id. at 20 (citing 2-Tr. 155-58). The special master accepted this argument in support of his finding that A.M.'s global developmental delay preceded his MMR vaccination. See id. at 19-20.

In addition, petitioners did not object to the special master's reliance on two MRI studies of A.M.'s brain, taken on March 24, 1998 and October 1, 1998, the latter of which showed "no interval change and no sign of progression of demyelination several months later." Id. at 21 (citing 2-Tr. 162-64). In evaluating the results of the two MRI

studies, Dr. Kohrman opined that “that the process involved in A.M.’s case is a static process rather than an ongoing process,” and such process was “consistent with a demyelinating or dysmyelinating process that produced [the] longstanding developmental delay dating back to his examination at the age of two years.” Id. (citing 2-Tr. 162-64).

The special master pointed out that while Dr. Souayah agreed there was no interval change in A.M.’s two MRI studies, unlike Dr. Kohrman, Dr. Souayah provided no opinion on the implication of those results. Id. (citing Ex. 24 ¶ 28). The special master found that Dr. Kohrman’s opinion on the MRI studies, unrebutted by Dr. Souayah, also supported a finding that A.M.’s global developmental delay preceded his MMR vaccination. See id. at 21-22.

As petitioners made no objection to these aspects of the evidentiary record relied upon by the special master, it is unnecessary for the court to determine whether the special master’s reliance on them was arbitrary or capricious. Nonetheless, having reviewed both Dr. Malinowska’s evaluation, the reports of A.M.’s parents to three different doctors, and the opinions of both Dr. Souayah and Dr. Kohrman regarding A.M.’s MRI studies, it is clear the special master’s opinion regarding this evidence finds support in the record, and that any inferences drawn from the evidence were plausible.

## 6. Conclusion Regarding the Special Master’s Onset Finding

The special master concluded that petitioners failed to show that the MMR vaccination caused A.M.’s injury because he found that onset of A.M.’s global developmental delay preceded his MMR vaccination. Because the special master’s decision shows that he carefully considered the relevant evidence in reaching this finding, drew plausible inferences, and articulated a rational basis for his decision, petitioners’ claim of reversible error is “extremely difficult to demonstrate.” Lampe, 219 F.3d at 1360 (quoting Hines, 940 F.2d at 1528).

To prevail on their motion, petitioners would, in effect, have to show that there was “no factual basis [whatsoever] . . . under which the decision could be justified.” Munn, 970 F.2d at 871. But this court cannot reweigh the evidence considered by the special master, if his “conclusion was based on evidence in the record that was not wholly implausible,” and in such circumstances, the court is “compelled to uphold [the special master’s] finding as not being arbitrary or capricious.” Lampe, 219 F.3d at 1363.

It is clear that petitioners seek a reweighing of the evidence. Petitioners urge that the contemporaneous records—specifically A.M.’s well-child examinations at the Addabbo Center and with Dr. Weiler—show normal development prior to his MMR vaccination, and thus contrary to the special master’s finding, show that the onset of A.M.’s global developmental delay was after his MMR vaccination. See Pet’rs’ Mot. 8.

Petitioners are correct that the portion of Dr. Kohrman's opinion that was based on the Addabbo Center records and Dr. Weiler's records was not well-supported. See supra Part III.A.1. The special master's decision, however, was not based solely, or even largely, on those records.

The special master's decision was well-supported by his consideration of and reliance on a number of other records, including: Dr. Maytal's March 2, 1998 diagnosis of longstanding global delay in language/communicative and fine motor skills; Dr. Malinowska's September 7, 1998 diagnosis of delay in the communication, daily living skills and motor skills domains, and A.M.'s parents' repeated reports that, at that time of his July to late September 1998 evaluations, A.M. had suffered no cognitive regression; and Dr. Kohrman's interpretation of the two MRI studies of A.M.'s brain taken in 1998. See supra Parts III.A.2, III.A.5. The special master's decision was also supported by his finding that Dr. Kohrman was more persuasive in his opinion than was Dr. Souayah in his opinion. See supra Part III.A.4.

Where "the special master's conclusion was based on evidence in the record that was not wholly implausible, [this court is] compelled to uphold that finding as not being arbitrary or capricious." Lampe, 219 F.3d at 1363. It is clear that the special master based his finding that the onset of A.M.'s global developmental delay preceded his MMR vaccination on reliable evidence in the record. Accordingly, petitioners have failed to show that the special master's decision was arbitrary or capricious.

#### B. Petitioners' Objection to the Special Master's Alternative Findings

Finally, petitioners object to the special master's alternative findings. First, petitioners state that the "diagnosis that best characterizes A.M.'s condition is spastic diplegia," not "infection from a post-vaccination, and/or an idiopathic language delay manifesting as a deficit in language that existed pre-vaccination." Pet'rs' Mot. 16-17. Petitioners also assert that there is no support in the record for the special master's "determination that A.M.'s condition was caused by sore throat," id. at 7, 16-17, and assert that the onset of A.M.'s symptoms, twenty-two days after receipt of his MMR vaccination, showed an appropriate temporal relationship, id. at 15-18.

The special master's findings that A.M. did not suffer an encephalopathy or encephalitis, Decision 23-26, that even if he did suffer such an injury, the more likely cause was an infection, id. at 27, and that the timing of A.M.'s first reported symptom of limping did not fit the timeframe discussed in the medical literature in the record, id. at 24-25, 28-29, 36, were all in the alternative to his primary finding that petitioners had not shown that the MMR vaccination caused A.M.'s injury as the onset of his global developmental delay preceded his vaccination.

As petitioners have not shown that the special master's finding that the onset of A.M.'s global developmental delay preceded his MMR vaccination was arbitrary or capricious, that finding alone is sufficient to support the special master's decision denying petitioners' petition for compensation. See Lampe, 219 F.3d at 1363 (compelling the court to uphold a special master's conclusion based on record evidence that is not wholly implausible). It is thus unnecessary for this court to consider petitioners' objections to the special master's three alternative findings.

IV. Conclusion

The special master's denial of petitioners' claim was not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Accordingly, the court **DENIES** petitioners' motion for review and **SUSTAINS** the decision of the special master. The Clerk of the Court shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Patricia Campbell-Smith  
PATRICIA CAMPBELL-SMITH  
Chief Judge